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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,672	10/23/2007	Andrew Kung	20363-025 NATL	2840

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Boston, MA 02111

7590 01/22/2009

EXAMINER

YAO, LEI

ART UNIT	PAPER NUMBER
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1642

MAIL DATE	DELIVERY MODE
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01/22/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/590,672		KUNG ET AL.	
	Examiner		Art Unit	
	LEI YAO		1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-59 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-17, drawn to a method of inhibiting tumor cell growth in a subject comprising administering a **cytotoxic or chemotherapeutic agent in combination with IGF-1R inhibitor**.

Group 2, claim(s) 18-32, drawn to drawn to a method of inhibiting tumor cell growth in a subject comprising administering **a compound comprising somatostatin which lower the concentration of IGF-1R inhibitor**.

Group 3, claim(s) 33-38, drawn to a method of inhibiting tumor cell growth in a subject comprising administering **IGF-1R inhibitor and anti-diabetic agent**.

Group 4, claim(s) 39-43, drawn to a method of inhibiting tumor cell growth in a subject comprising administering **a compound that decreases the expression of IGF-1R, wherein the compound is siRNA or antisense nucleic acid**.

Group 5, claim(s) 39-41 and 43-47, drawn to a method of inhibiting tumor cell growth in a subject comprising administering **a compound which decreases the activity of IGF-1R, wherein the compound is antibody, antagonist, or small molecule inhibitor**.

Group 6, claim(s) 48-53, drawn to a method of **reducing angiogenesis** in a tissue, comprising contacting tissues with **IGF-1R inhibitor**.

Group 7, claim(s) 54-59, drawn to a method of **inducing apoptosis** in a cell comprising contacting cells with **IGF-1R inhibitor**.

According to PCT rule 13.2, unity of invention exists only when there is a shared same or corresponding special technical feature among the claimed inventions. All the groupings are directed to methods of inhibiting tumor/angiogenesis or induce apoptosis but each group has ad different special technical feature not sheared by the remaining groups. Group 1 is directed to a method of inhibiting tumor cell growth comprising administering a cytotoxic or chemotherapeutic agent and IGF-1R inhibitor, which has the special technical feature of using chemotherapeutic or cytotoxic agent not shared by any of the remaining groups.

Group 2 is directed to a directed to a method of inhibiting tumor cell growth comprising administering compound comprising somatostatin which has the special technical feature of a compound that lower the concentration of IGF-1R inhibitor not sheared by any of the remaining groups.

Group 3 is directed to a directed to a method of inhibiting tumor cell growth comprising administering IGF-1R inhibitor and anti-diabetic agent which has the special technical feature of using anti-diabetic agent not sheared by any of the remaining groups.

Group 4 is directed to a directed to a method of inhibiting tumor cell growth comprising administering compound comprising siRNA or antisense nucleic acid which has the special technical feature of using nucleic acid not sheared by any of the remaining groups.

Group 5 is directed to a directed to a method of inhibiting tumor cell growth comprising administering a compound comprising an antibody or small molecule

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inhibitor, which has the special technical feature of antibody or small molecule not sheared by any of the remaining groups.

Group 6 is directed to a directed to a method of reducing angiogenesis in a tissue, comprising contacting tissues with IGF-1R inhibitor which has the special technical feature of treating angiogenesis with IGF-1R inhibitor alone not sheared by any of the remaining groups.

Group 7 is directed to a directed to a method of inducing apoptosis in a cell comprising contacting cells with IGF-1R inhibitor which has the special technical feature of inducing apoptosis not sheared by any of the remaining groups.

Election/Species

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are in the following groups:

A. Cytotoxic agent, chemotherapeutic agent (further elect a, b, or c)

- a. doxorubicin
- b. melphalan
- c. dexamethasone

B. Hyperglycemia, ketosis, glucosuria.

C. Glycosidase inhibitor, small molecule tyrosine kinase inhibitor (further elect i or ii), anti-IGF-1R antibody, IGF-1R antagonist.

- i, ADW-742
- ii. NVP-AEW541

D. Insulin polypeptide, insulin sensitivity enhance (further elect 1, 2, or 3), insulin secretion enhancer.

1. thiazolidinedione,
2. biguanide,
3. glucosidase inhibitor

E. Mechanisms listed in claim 43.

F. siRNA or antisense nucleic acid.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

Applicant elects any invention from group 1-3 and 5-7 above, Applicant is required to elect one IGF inhibitor from group C. For example, elect anti-IGF-1R antibody OR elect tyrosine kinase inhibitor and further elect ADW-742.

If Applicant elects invention group 1, Applicant is required to further elect one species from A and one species from B.

If Applicant elects invention group 3, Applicant is required to further elect one species from D.

If Applicant elects invention group 4, Applicant is required to further elect one species from F.

If Applicant elects invention group 5, Applicant is required to further elect one mechanism (method step) listed in claim 43 (E). For example, elect method step of determining inhibiting intracellular trafficking of the IGF-1R.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEI YAO whose telephone number is (571)272-3112. The examiner can normally be reached on 8am-5 pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lei Yao/
Examiner, Art Unit 1642

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/Larry R. Helms/

Supervisory Patent Examiner, Art Unit 1643